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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,562	08/16/2006	Klaus Abraham-Fuchs	32860-001072/US	8548
30596 7590 06/30/2010 HARNESS, DICKEY & PIERCE, P.L.C. P.O.BOX 8910 RESTON, VA 20195				
EXAMINER				
PASS, NATALIE				
ART UNIT		PAPER NUMBER		
3686				
NOTIFICATION DATE		DELIVERY MODE		
06/30/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

demailroom@hdp.com
siemensgroup@hdp.com
pshaddin@hdp.com

Office Action Summary

Application No.

10/589,562

Applicant(s)

ABRAHAM-FUCHS ET AL.

Examiner

Natalie A. Pass

Art Unit

3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 24 March 2010. Claim 1 has been amended. Grounds of rejection for claims 1-12 are set forth in detail below.

Claim Rejections - 35 USC § 101

2. Claims 1-12 are rejected under 35 U.S.C. §101 for substantially the same reasons given in the previous Office Action (paper number 20091215). Further reasons appear hereinbelow.

(A) Claim 1 has been amended to recite "using a data processing system" throughout the body of the claim. Examiner notes that, as stated in the previous Office Action, an example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state. In the instant application, Appellant's method steps continue to fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. Examiner respectfully submits that a person engaged in thinking is also "using a data processing system"

and that a pencil and paper is another form of a "data processing system." Accordingly, the amendment fails to overcome the rejection of claims 1-12 under 35 U.S.C. §101.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 4-5, 7, 10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson et al. (2002/0002474), for substantially the same reasons given in the previous Office Action (paper number 20091215). Further reasons appear hereinbelow.

(A) As per the amendments to claim 1, these appear to have been made merely to correct errors in the claim language and to correct claim rejections in the prior Office Action under 35 U.S.C. 101. While these changes render the language of the claims smoother and more consistent, they otherwise affects neither the scope and breadth of the claims as originally presented nor the manner in which the claims were interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 20091215, section 5, page 4), incorporated herein.

(B) Claims 2, 4-5, 7, 10, 12 have not been amended and are rejected for the same reasons given in the previous (paper number 20091215, section 5, page 4), and incorporated herein.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 6, 8-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson et al. (2002/0002474).

(A) Claims 3, 6, 8-9, 11 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 20091215, section 7, pages 5-6), and incorporated herein.

Response to Arguments

7. Applicant's arguments filed 24 March 2010 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 24 March 2010.

(A) At pages 6-7 of the response filed 24 March 2010, Applicant argues that the features in the 24 March 2010 amendment are not taught or suggested by the applied reference. In response, all of the limitations which Applicant disputes are missing in the applied reference, including the features newly added in the 24 March 2010 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the teachings of Michelson, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the 35 USC §102 and §103 rejections given in the preceding sections of the present Office Action and in the prior Office Action (paper number 20091215), and incorporated herein. In particular, Examiner submits that the Michelson reference teaches calculating the likelihood of the feasibility of the medical project. Examiner submits that Applicant's own specification describes this limitation as follows: "[a]s a measure of the feasibility of the project, for example, it is thus possible to calculate a simple Yes/No appraisal or a likelihood that it will be carried out successfully" (Specification; page 6, paragraph 1). Examiner interprets Michelson's teachings of "[t]he data sets and search parameters used to conduct searches in the TIA databases have been created to conform to the information required by clinical study sponsors when determining the likelihood of recruitment success within the projected time frame for a particular protocol for the study ... [...]..." (Michelson; paragraph [0087]) and "the inventive system may be linked to the systems of other entities involved in the clinical studies process, thereby creating an automated clinical studies system from compound development through study feasibility and subject/investigator recruitment, study conduct and post-study marketing" (Michelson; paragraph [0116]) to teach a form of this limitation.

As such, it is unclear as to how or why Appellant's claimed limitations are not met by at least the aforementioned passages. Perhaps Appellant is relying on features not expressly recited in the claims, but disclosed in the specification. However it has been held that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to Applicant's arguments on page 6 of the response filed 24 March 2010 that "Michelson does not disclose quantitatively calculating a likelihood or probability of the feasibility of the study," Examiner respectfully notes that this is not a claimed limitation.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any response to this final action should be mailed to:

Box AF
Commissioner of Patents and Trademarks
Washington D.C. 20231

or faxed to: (571) 273-8300.

For formal communications, please mark "EXPEDITED PROCEDURE".

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on 9-6:30 Monday - Thursday and alternate Fridays.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3686
June 24, 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686